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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,873	01/18/2002	Steven M. Ruben	PZ029P2	6536

22195 7590 05/18/2004

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,873	RUBEN ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-28 and 30-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28 and 30-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/22/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1a. Receipt of Applicants' amendment and arguments filed on 27 February 2004 is acknowledged. Claims 1-24, 29 have been cancelled. Thus claims 25-28 and 30-45 are pending and under consideration.

1b. References AF, AG, AH, AI, AJ, AK, AL, AM, AN and AO, cited on the PTO-1449 form submitted by Applicants on 22 September 2003, have now been considered. Applicants are thanked for providing the copies of these references.

2. The following previous objection is withdrawn in light of Applicants amendments filed on 02/27/04:

2a. The objection to specification is withdrawn.

2b. All of the objections and rejections made against claims11 and 29 are withdrawn, since these claims have been cancelled.

2c. The rejection of claims 36-45 made under 35 U.S.C. 112, first paragraph, for not providing deposit information is withdrawn.

Response to Applicants' arguments:

3 Applicant's arguments and amendment filed on 02/27/04, have been fully considered but were deemed persuasive in part. The remaining issues follow.

Claim Rejections under 35 U.S.C. §101/112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 25-28 and 30-45 stand rejected under 35 U.S.C. §101, for reasons of record, set forth in the office action mailed on 12/17/03, pages 4-6, and reiterated here,

because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Applicants submit the following arguments regarding this rejection.

Applicants argue that the Examiner has not made a prima facie case for why the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, and that the Examiner just made generalized statements as to why the specification does not provide any evidence that the claimed polypeptide is indeed involved in any utility. Applicants contend that the instant specification teaches that the claimed polypeptides are expressed in specific tissues including endometrial, adenocarcinoma and breast cancer. Therefore, the polypeptide of the instant invention has an asserted specific utility, because it may be useful in diagnosis and/or treatment of those specific cancers. Furthermore, Applicants submit that diagnosing or treating these specific cancers is certainly a "real world" use, thus the skilled artisan would find the assertion of utility to be substantial. Applicants point out that they do not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty or provide actual evidence of success in treating human where such utility is asserted. Applicants cite the M.P.E.P § 2107 (III), where courts have found "that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an immediate benefit' and thus satisfies that utility requirement." All that is required of Applicants is that there be a reasonable correlation between the biological activity and the asserted utility. See Nelson v. Bowler, 626 F.2d 853, 857 (C.C.P.A. 1980). Finally

Applicants argue that one of ordinary skill in the art would have no basis for considering the asserted utilities to be "false" and that the claimed invention meets at least one stated objective under 35 U.S.C §101.

Applicants' arguments have been considered fully but are deemed unpersuasive. Firstly, the Examiner has made a prima facie case for why the claimed invention lacks an asserted specific utility or well established utility. The examiner addressed each and every asserted utility and why it is not specific or substantial or well established, (see the office action mailed on 17 December 2003). Secondly, although, the instant specification states that the *gene* of the instant invention is expressed in specific tissues including endometrial, adenocarcinoma and breast cancer, the specification does disclose whether the claimed polypeptide is also expressed in these cancer tissues. Neither does the specification compare the expression of the gene or the encoded polypeptide in cancerous tissues to normal tissues. Furthermore, even if the expression of the gene in cancerous tissues is increased, it does not necessarily follow it would result in increased protein expression. Thus, while the nucleic acid itself might be useful diagnostically if its expression is increased in certain cancerous tissues compared to normal tissues, the encoded polypeptide would not be useful diagnostically or as target for cancer drug development. For example, Pennica et al, (1998, PNAS USA 95:14717-14722) discloses that, "An analysis of WISP-1 gene amplification in human colon tumors showed a correlation between DNA amplification and over expression, whereas, over expression of WISP-3 RNA was seen in the absence of DNA amplification. In contract, WISP-2 DNA was amplified in the colon tumors, but mRNA expression was

significantly reduced in the majority of tumors compared with the expression in normal colonic mucosa from the same patient", see page 14722, second paragraph of column 1; pages 14720-14721. Therefore, the protein levels cannot be accurately predicted from the level of the corresponding gene, because the art indicates that it is not the norm that gene amplification or increased transcription results in increased protein level. Accordingly, showing that the DNA encoding the claimed polypeptide is increased in certain cancerous tissues, is not sufficient to establish any utility for the protein encoded thereby. Thirdly, Applicants are correct in that diagnosing or treating specific cancers is a "real world" utility, however, the instant specification does not disclose any cancer that can be diagnosed or treated using the claimed polypeptide. Fourthly, although an Applicant does not have to prove that there is a correlation between a particular activity and an asserted therapeutic use, or provide an evidence of success in treating humans, he has to disclose a sound scientific reasoning as to why the compound would be effective in said treatment. Furthermore, proper controls must be done addressing whether there are any undesirable side effects. In inre Nelson, (Nelson v. Bowler, 626 F.2d 853, 857 (C.C.P.A. 1980)), to support the asserted utility identified in his disclosure, Nelson included in his application the results of tests demonstrating the bioactivity of his new substituted prostaglandins relative to the bioactivity of naturally occurring prostaglandins. The court concluded that Nelson had satisfied the practical utility requirement in identifying the synthetic prostaglandins as pharmacologically active compounds. In reaching this conclusion, the court considered and rejected arguments advanced by Bowler that attacked the evidentiary basis for Nelson's assertions that the

compounds were pharmacologically active. However, instant Applicants do not provide an activity for the claimed polypeptide, nor a reasonable correlation between a biological activity and the asserted utility, nor do they provide the physiological significance of this polypeptide, only, an assertion that it can be used therapeutically. Finally, Applicants have not provided one single a specific and substantial asserted utility or a well established utility for the claimed polypeptide.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4b. Claims 25-28 and 30-45 stand under 35 U.S.C. 112, first paragraph for reasons of record, set forth in the office action mailed on 12/17/03, pages 6-7. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Showing that the gene of the instant invention is increased in certain cancerous tissues, is not sufficient to establish any utility for the claimed polypeptide.

Conclusion:

5. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
14 May 2004

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER